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Evaluation of a New, Semiquantitative Screening Culture Device for Urine Specimens

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The EZ Streak urine culture device (Difco Laboratories, Detroit, Mich.) combines the advantages of both the dip-slide and the classic urine culture technique, enabling bacterial enumeration and isolation following a simple inoculation step. Five hundred clean-catch urine specimens submitted by outpatients attending a health maintenance organization were used to compare the EZ Streak with culture using a 0.001-ml loop. Complete agreement of colony counts determined by the two methods was obtained for 114 (91.2%) of 125 positive specimens, but 99.2% of the results agreed in clinical interpretation, indicating the presence or absence of bacteriuria. Overall agreement between the EZ Streak and culture was 95.7%. The sensitivity and specificity of the EZ Streak were determined to be 98.4 and 99.4%, respectively. For this patient population, the EZ Streak was determined to be a reliable replacement for routine urine culture.

An increasing amount of health care delivery is being accomplished through group practices, health maintenance organizations (HMO), and outpatient settings. The emergence of health care reform may broaden these delivery systems to an unprecedented degree. Urine specimens collected at distant sites pose special problems because of the potential for overgrowth of commensal flora unrelated to the clinical diagnosis, thus obscuring the true etiologic agent (1).

Current methods for bacteriologic examination of urine are culture (2, 3) and the dip-slide method (6). Several rapid screening methods have been proposed and evaluated (7), but their use has been limited by the lack of sensitivity when pathogens are present in low numbers. Timely transport of urine specimens to the laboratory or use of refrigeration or preservatives (3) is critical for the production of accurate laboratory data from these specimens. For the clinical laboratory, the culture method using a calibrated loop provides the semiquantitative results to which clinicians have become accustomed. For physicians' offices and off-site facilities, the easiest and most convenient means of determining the presence or absence of bacteria in urine might be a dip-slide procedure that requires little expertise to perform. Some hospital laboratories have found these devices to be helpful (5).

The EZ Streak urine culture device (Difco Laboratories, Detroit, Mich.) was recently introduced into the United States and reportedly combines the advantages of both the dip-slide and the classic culture technique, enabling bacterial enumeration and isolation following a simple, user-friendly inoculation step. The EZ Streak, first reported as the Diaslide (8), has not been evaluated in a clinical setting in the United States but may offer an effective alternative to routine plating requirements for health care providers in a variety of settings. This study compared the results of inoculation and culture of urine with the EZ Streak with those of routine culture in an HMO setting.

Specimens. Urine specimens for culture and susceptibility testing were selected at random from 500 clean-catch specimens from an out-patient population of an HMO. Specimens for analysis were not evaluated on the basis of patient age, sex, medical history, or antibiotic therapy. Specimens were submitted in screw-cap urine containers and consisted of at least 10 ml of urine.

Culture. Specimens arriving at the laboratory were inoculated onto a blood agar plate and a colistin-nalidixic acid agar–MacConkey biplate by using a 0.001-ml calibrated loop and by using the EZ Streak urine culture device.

The well-mixed urine was sampled with the calibrated loop and plated onto the surface of the blood agar plate. A single streak of the inoculum was spread across the center of the plate, and the inoculum was then spread perpendicular to the primary streak to ensure a semiquantitative colony count. Each side of the colistin-nalidixic acid agar–MacConkey plate was inoculated in the same manner. Plates were incubated at 35°C and examined once at 18 to 24 h. If no growth was observed or if the colony count was less than 10 CFU per plate, the plates were kept for an additional 24 h and read again. Positive cultures and obviously contaminated cultures were reported at 24 h.

In this study, a contaminated culture was defined as one containing three or more organisms or one exhibiting growth of *Lactobacillus* sp. or diphtheroids.

The EZ Streak was inoculated and interpreted in accordance with the instructions of the manufacturer as follows. The device was removed from its packaging, and the sampler tips were dipped into the mixed urine sample while making certain that both tips were immersed completely. After the tips were charged with urine, the sampler was withdrawn through the casing, automatically inoculating each side of the agar paddle device. The sampler was discarded, and the agar-containing device was recapped and incubated along with the routine agar at 35°C. Devices that exhibited no growth or <10 CFU per plate at 18 to 24 h were reincubated overnight. Colonies were counted and compared to illustrations provided by the manufacturer.

Interpretive criteria. Urine culture results were grouped into three categories as described by the manufacturer. A positive urine culture was interpreted as having ≥100,000 CFU/ml. A borderline urine culture (according to the manufacturer) contained 10,000 to 100,000 CFU/ml. A negative culture had <10,000 CFU/ml or exhibited no growth. Organisms in positive and borderline cultures were identified and tested for

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TABLE 1. Comparison of results of routine urine culture with the Difco EZ Streak urine culture device

Culture results	No. of EZ Streak results:			
	Positive[a]	Negative	Contaminated	Total
Positive	124	2	0	126
Negative	1	174	6	181
Contaminated	0	43	150	193
Total	125	219	156	500

[a] Positive, $\geq 10^4$ CFU/ml; negative, $\leq 10^4$ CFU/ml (including no growth); contaminated, contaminated specimens included lactobacilli, diphtheroids, and more than two colony types per plate.

susceptibility to antimicrobial agents and were both considered positive for our analysis.

In the present study, 500 clean-catch urine samples were received from an HMO population. Table 1 summarizes the results. From this population, 125 specimens (25%) were positive ($>10^5$ CFU/ml) or borderline (10^4 to 10^5 CFU/ml), and in our laboratory, the results would have been reported to the physician. All but three positive specimens were pure cultures. Since this positivity rate matched the rate usually achieved in this HMO facility, we considered the relatively small sample size of 500 patients adequate for determination of the sensitivity and specificity of the EZ Streak in our patient population compared with those of our routine method of culture with a 0.001-ml loop. In most cases, information regarding patient symptoms was unavailable on the laboratory request form. We recognize the value of such information for interpretation of culture results when low numbers of organisms are isolated (2, 3); however, in this study, we used the colony counts recommended by the manufacturer to categorize urine culture results for comparison. We did not evaluate clinical outcome.

The culture method and the EZ Streak provided the same colony counts for 114 (91.2%) of the 125 test specimens considered positive, but the results would have been interpreted in our laboratory as positive for both methods 99.2% of the time. Ten specimens provided counts of $>10^5$ CFU/ml (positive) by one method and 10^4 to 10^5 CFU/ml (borderline) by the other. While these did not exhibit exactly the same colony counts, our in-house interpretive criteria would have classified them all as positive, requiring identification and reporting.

Of 174 uncontaminated negative specimens exhibiting either no growth or colony counts of $\leq 10^4$ CFU/ml, 153 (88%) had the same colony counts with both methods. Twenty-one specimens (12%) showed no growth by one method or $\leq 10^4$ CFU/ml (negative) by the other, both being interpreted as negative and receiving no further analysis. One specimen grew $\geq 10^5$ *Lactobacillus* sp. CFU/ml by the calibrated-loop method but exhibited no growth on the EZ Streak. The EZ Streak did support the growth of *Lactobacillus* sp., since 15 of 16 isolates of *Lactobacillus* sp. grew on the paddle device while 7 of 16 were recovered by routine culture.

The contamination rate for this study was defined as more than two species isolated from a clean-catch urine specimen. We experienced a high contamination rate (38.6%), partly because of the outpatient nature of the patient population and collection process and the lack of control in providing the necessary directions to the patients. However, for 166 (86%) of 193 contaminated specimens, the same number and types of contaminants were found with both systems. For 11 of 193 specimens determined by routine culture to be contaminated, the EZ Streak exhibited no growth. In one case, the EZ Streak detected more than two colony types at a level of 10^4 to 10^5 CFU/ml while routine culture exhibited no growth.

We found that the EZ Streak was unable to support the growth of group A streptococci from urine. The urine isolate we encountered was found in the 10^4 to 10^5-CFU/ml range. To determine if the lower count affected its appearance on the EZ Streak cystine lactose electrolyte deficient CLED medium, we prepared dilutions of the urine isolate and a control strain, ATCC 19615. The EZ Streak was unable to support the growth of either of the group A strains, even at concentrations as high as 10^8 CFU/ml. Group B streptococci did grow on the medium on the paddle device.

The overall test accuracy was calculated by dividing the sum of the true positive, true negative, and borderline reactions (where the EZ Streak and culture agreed) by the sum of positive, negative, and borderline culture results used as standards. Compared to culture, the EZ Streak had an overall test accuracy of 95.7%. From the data in Table 1, where the borderline results were included as positive, the sensitivity and specificity of the EZ Streak compared to culture were 98.4 and 99.4%, respectively.

The EZ Streak contains CLED agar and MacConkey agar. MacConkey agar supports the growth of most gram-negative isolates and uses lactose utilization as a means of differentiation. CLED agar supports the growth of both gram-positive and gram-negative bacteria, providing color changes that help in preliminary identification, especially of lactose-fermenting organisms, which change the color of the medium from green to yellow (4). The low salt content of the medium also inhibits the swarming of *Proteus* sp. The manufacturer does not specify the amount of urine that is captured on the sampler tips. Instead, photographs are provided illustrating the relative correlation of the growth on the agar with that derived from a calibrated loop. In most cases, when colonies could be counted on routine media, they could also be counted on the EZ Streak agars. Isolated colonies could easily be picked from the agar paddles and prepared for identification and susceptibility testing.

The EZ Streak combines the advantages of ease and convenience of inoculation of a urine dip-slide procedure with the quantitation offered by a calibrated loop method. In this study, the EZ Streak was inoculated in the laboratory to control the technique but we soon realized that even inexperienced health care workers could correctly inoculate the device and either send it to the laboratory for incubation or incubate it in the examining office and send the device to the laboratory the next day for evaluation and work-up. Under the Clinical Laboratory Improvement Amendment of 1988, some paddle-type urine colony count devices can be inoculated and incubated in a physician's office or a laboratory approved for moderate-complexity tests. Evaluation of colony counts only for recognition of bacteriuria is also considered a moderate-complexity test, but further work-up and any identification of bacteria is considered a high-complexity test.

The advantages of the EZ Streak in our study were speed and ease of inoculation, less incubator space required, reduced turnaround time at after-hours facilities, ability to use rapid preparation devices for susceptibility test suspensions, and less storage space required than for plate media. The disadvantages include a difficult-to-open plastic package, lack of familiarity with the value of CLED agar, lack of ability to support the growth of group A streptococci, and provision by the manufacturer of broad interpretive standards rather than distinct colony counts. In addition, an occasional specimen produces a "rollback" phenomenon whereby an excess urine droplet runs down the paddle when the inoculator is removed, causing difficulty in obtaining isolated colonies.

A complete clinical evaluation of the EZ Streak requires testing of many more urine specimens and analysis of the

efficiency of the media for supporting a larger variety of urinary pathogens. However, in a smaller patient population and in unique settings where health care providers are scattered and distant from a central laboratory, a limited evaluation of the effectiveness of the new paddle device was in order.

We believe that the advantages of using the EZ Streak in the HMO setting outweigh the disadvantages. We found the device to be effective in providing accurate semiquantitative urine culture results for patients in an HMO setting. The results of the EZ Streak paralleled those of routine culture with a calibrated loop and can provide a cost-effective alternative to urine culture in this patient population.

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